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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/701,031 | 11/22/2000 | Hannele Tolo | 0365-0476P | 4589 |

7590 05/17/2002

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Falls Church, VA 22040-0747

EXAMINER

ANDRES, JANET L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1646

DATE MAILED: 05/17/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,031

Applicant(s)

TOLO ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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RESPONSE TO AMENDMENT

1. Applicant's amendment filed 27 February 2002 is acknowledged. Claims 1-18 are pending in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The rejection of claims 1-8 and 11-15 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

Claim Rejections Maintained/New Grounds of Objection/Rejection

3. The use of the trademarks has been noted on p. 2 of this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

The specification is objected to because it refers to claim 1 and claim 15 on p. 4. Claims may be renumbered, amended, or cancelled, rendering the reference incorrect. In addition, the claims must be supported by the specification, rather than the reverse. The specification should be amended to incorporate the information contained within the claims.

4. The rejection of claims 9 and 10 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record in paper no. 5. It is not clear whether the solutions are prefiltered or sterile filtered before or after the detergent is added.

5. The rejection of claims 1-15 under 35 U.S.C. 103 is maintained and applied to new claims 1-18.

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Applicant argues that the combination of the Georgiades '683 patent with the Manabe '315 patent is improper, because the '683 patent uses albumin. Applicant argues that the addition of albumin would result in inefficient removal. Applicant further argues that citing references that merely indicate that isolated elements are known is not a sufficient basis for concluding that the claimed invention would be obvious, and argues that the combination would render the prior art version unsatisfactory for its intended purpose. Applicant additionally points to claims 8 and 16-18 as specifically excluding albumin.

Applicant's arguments have been fully considered but have not been found to be persuasive. While the '683 patent refers to the addition of albumin as a stabilizer in Example 1, there is nothing either in the description of the invention or the claims that requires its addition. It is not necessary for omission of albumin to be the preferred embodiment of the '683 patent. One of ordinary skill would know, on reading the disclosure, that its addition was not needed, since albumin is mentioned neither in the description of the invention nor the claims. Further, the cited references do not teach isolated elements. As stated in the previous office action, the '683 patent teaches detergent addition as a means of virus inactivation and teaches that membrane filtration is an additional means of virus inactivation. The '315 patent teaches a membrane filter explicitly for removing viruses. One of ordinary skill in the art, therefore, on reading the '683 disclosure, would know that detergent could be used to inactivate virus and that an additional step of filtration would also be useful. Thus, it would be obvious to one of ordinary skill in the art to use a filter such as is taught in the '315 patent in combination with detergent to obtain maximal virus removal, because the '683 patent suggests such a combination. Further, as

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stated previously, the fact that the two procedures are directed to same purpose renders it *prima facie* obvious to combine them; see *In re Kerkhoven*, cited previously.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

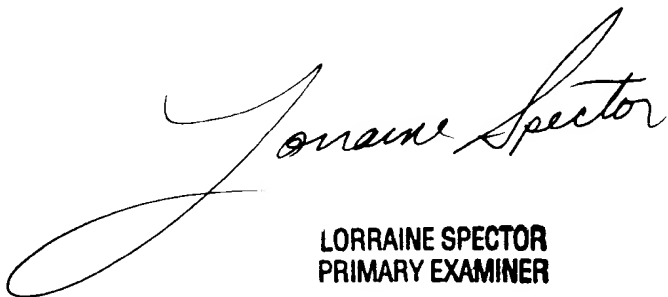
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Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [\[jyvonnie.eyler@uspto.gov\]](mailto:jyvonnie.eyler@uspto.gov).

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
May 9, 2002



LORRAINE SPECTOR
PRIMARY EXAMINER